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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/995,277

Applicant(s)  
Baell et al.

Examiner  
Phyllis G. Spivack

Art Unit  
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 27, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 108-111, 113, 116, 122-142, and 145 is/are pending in the application.
- 4a) Of the above, claim(s) 135 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 108-111, 113, 116, 122-134, and 136-142 is/are rejected.
- 7) ☒ Claim(s) 145 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) (Paper No(s). \_\_\_\_\_)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Art Unit: 1616

Applicant's Amendment filed September 27, 2002, Paper No. 9, is acknowledged. Claims 112, 114, 115, 117-121, 143, 144 and 146-150 are canceled. Claims 108-111, 113, 116, 122-134, 136-142 and 145, directed to the compositions and methods of use of Group I, wherein at least one of  $W^1$  and  $W^2$  is  $CO_2R^3$  and the other is  $CO_2R^3$ ,  $C(=NH)NH(OH)$  or  $C(=O)CF_3$ , and wherein no other heteroaryl groups are present, remain under consideration.

Claim 135 is withdrawn from consideration by the Examiner, as being directed to a non-elected invention, 37 CFR 1.142(b).

In the last office action claims 108-112 and 122-141 were rejected under judicially created doctrine as being drawn to an improper Markush group. It was asserted a proper Markush group must share a substantial structural feature disclosed as being essential.

Applicants urge cancellation of claims 112, 114, 115, 117-121, 143, 144 and 146-150 from the instant application and amendment of claim 108 to remove non-elected subject matter, as suggested by the Examiner, resolve the issue.

It is noted each of  $Ar^1$  and  $Ar^2$  may be heteroaryl in claim 122. It is further noted the compound of claim 135 may be nucleoside. Accordingly the Markush rejection of record is maintained with respect to claim 108-111, 113, 122-134, 136-141 and extended to include claim 113.

Following the cancellation of claims 112, 114, 115, 117-121, 143, 144 and 146-150 from the instant application and the amendment of claim 108 to remove any overlapping subject matter with U.S. Patent No. 6,355,683, the rejection of claims 108-

Art Unit: 1616

150 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,355,683, is withdrawn.

In the last Office Action claims 108-111 and 122-141 were rejected under 35 U.S.C. 112, both first and second paragraphs, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make the invention, and, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In response, claim 108 and claims dependent therefrom have been amended to more narrowly recite the claimed linker group L within the Examiner's restriction group I. Applicants have canceled Claim 112 and amended Claim 113 to depend from Claim 108, which provides sufficient antecedent basis, as amended. Applicants have amended Claim 141 to remove the recitation to L<sup>1</sup>.

Because no amendments in response to the rejections of record under 35 U.S.C. 112, both first and second paragraphs, were applied to the method claims, these rejections are maintained with respect to claims 122-134 and 136-142.

Claims 108-112 were rejected under 35 U.S.C. 102(b) as being anticipated by Riad et al., J. Chem. Res. Synop. (abstract), or Aizpurua et al., Can. J. Chem. (abstract) in the last Office Action. Based on the reference to claim 116, it is apparent claims 113 and 116 were inadvertently omitted but intended to be included in the rejection. It was asserted Riad and Aizpurua independently disclose the compound 4,4'-[oxybis(methylene)] bisbenzoic acid, the compound of instant claim 116, in a composition.

Art Unit: 1616

Applicants argue Riad and Aizpurua independently disclose the compound 4,4'-[oxybis(methylene)] bisbenzoic acid. The compound disclosed by the reference to Riad and Aizpurua is a benzylic ether whereas the compound of claim 116 is a phenolic ether. Furthermore, Riad and Aizpurua merely teach methods of synthesizing the benzylic ether and there is no mention or suggestion in either reference of the use of the benzylic ether in the applications of the instant invention.

The rejection is withdrawn because, as amended, the compounds disclosed by the references are not presently encompassed within the claimed subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 108-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Chucholowski et al., U.S. patent 5, 521, 160.

Chucholowski teaches pharmaceutical compositions comprising bis carboxystilbenes. For instance, see Examples 2 and 3, column 14.

Art Unit: 1614.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 108-111, 113 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanaka et al., U.S. Patent No. 5,932,575.

Yanaka teaches a pharmaceutical composition comprising a compound of formula I wherein  $Z = CH$ ;  $t = 0$ ;  $R^7 = -CO-$ ;  $R^2 = -OH$ ;  $R^{13} = H$ ;  $R^{12} = -R^{11}-R^5$ ;  $R^{11} = -O-$ ;  $R^5 = -CH_2C_6H_4COOH$ . See columns 1, -2. Yanaka states the compounds are known in the prior art. The claims differ only with respect to the position of the carboxyl group in  $R^5$ . However, one skilled in the art of formulation chemistry would have been motivated to prepare a composition comprising 3,3'-[oxybis(methylene)]bis-benzoic acid to treat cardiac diseases. Such would have been obvious in the absence of evidence to the contrary because it would have been reasonable to expect the three position isomers of such close structural similarity to exhibit the same pharmacologic activity.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

January 14, 2003

*Phyllis Spivack*  
PHYLLIS SPIVACK  
PATENT EXAMINER  
GROUP 1614